

REMARKS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, and 110 are pending, with claim 94 being the only withdrawn claim. By this amendment claims 25, 26, 27, 52, 53, 54, and 83 have been amended. Support for the amendments to the claims is provided, for example, at page 22 lines 19-21, page 29 lines 10-11, page 32 lines 14-15, and 33 lines 24-26. No new matter has been introduced.

The election of species remains: (1) durum wheat as the plasticized matrix material, (2) a probiotic neutraceutical component as an encapsulant, (3) starch as the additional matrix material, and (4) liquid encapsulant as the encapsulant form. The claims readable on the elected species are Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110.

Applicants thank the Examiner for withdrawing the previous rejections under 35 U.S.C. 103, and for making the present Office Action non-final.

THE REJECTION UNDER 35 USC 112, FIRST PARAGRAPH

Claims 31, 59, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner alleges that the terms “polyvinyl acetate and derivatives thereof” and “modified starches” are unclear since Applicant’s specification does not define at what point does modifying the core compound lead to a different compound that would not be considered a derivative or a modified starch encompassed by the instant invention.

According to the Manual of Patent Examining Procedure,

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*,

802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.").< If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

MPEP § 2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement [R-5].

Furthermore, the term "modified starch" and the extent of modification is well known to those skilled in the art as exemplified in the USPTO online Manual of Classification class definition for Class 127, subclasses 32, 33, and 38 (<http://www.uspto.gov/web/patents/classification/uspc127/defs127.htm>) :

32 Modified starches:
This subclass is indented under products . Starches which have been chemically modified or incipiently hydrolyzed either by the action of added reagents or by cooking or special heat treatments, but which still give a blue or violet reaction with iodine, and processes of making them.
SEE OR SEARCH THIS CLASS, SUBCLASS:
38, and indented subclasses, for hydrolysis of starch where it is carried to a point where the blue or violet reaction with iodine is no longer obtained.
33 Added chemical:
This subclass is indented under subclass 32 . Starches which have been chemically modified or hydrolyzed by the action of added reagents, but which give a blue or violet reacton with iodine and processes of making them.

Additionally, the term "derivative" is used extensively in the USPTO class definitions as exemplified by a search in the USPTO online Manual of Classification for the

term "derivative"

(http://search.usa.gov/search?query=+derivative&affiliate=uspto.gov&locale=en&m=&scope_id=PatentClass&commit=Search):

Results 1-10 of about 184 for 'derivative' follow:

Class Definition for Class 527 - SYNTHETIC RESINS OR NATURAL RUBBERS ...

D. a lignin, tannin, or derivative thereof, E. a reactant which is coal or bituminous material, an extract or derivative thereof, or a fatty still residue,

<http://www.uspto.gov/.../defs527.htm> - Cached

Class Schedule for Class 536 ORGANIC COMPOUNDS -- PART OF THE CLASS ...

This Class 536 is considered to be an integral part of Class 260 (see the Class 260 ...

Novobiocin or derivative

<http://www.uspto.gov/.../sched536.htm> - Cached

Class Schedule for Class 424 DRUG, BIO-AFFECTING AND BODY TREATING ...

Attached to carbohydrate compound; derivative thereof (e.g., DNA, nucleotide, nucleoside, sugar, starch, tannin, saccharide, polysaccharide, cellulose, O-, N- and S-glycoside ...

<http://www.uspto.gov/.../sched424.htm> - Cached

Class Schedule for Class 527 SYNTHETIC RESINS OR NATURAL RUBBERS ...

With di- or higher ester of polycarboxylic acid; or with polycarboxylic acid or derivative and a compound containing two or more hydroxyl groups or salts thereof as reactants

<http://www.uspto.gov/.../sched527.htm> - Cached

Class Schedule for Class 507 EARTH BORING, WELL TREATING, AND OIL ...

Organic component is carbohydrate or derivative thereof (e.g., sugar or gum, such as galactomannan, xanthan, etc.) or carboxylic acid ester of an alcohol which has five or more

...

<http://www.uspto.gov/.../sched507.htm> - Cached

Class Definition for Class 51 - ABRASIVE TOOL MAKING PROCESS ...

Cellulose or derivative thereof: This subclass is indented under subclass 302. Subject matter including (a) a process involving the use of cellulose or a derivative thereof or (b ...

<http://www.uspto.gov/.../defs051.htm> - Cached

Class Schedule for Class 525 SYNTHETIC RESINS OR NATURAL RUBBERS ...

Solid polymer derived from a lactam; from an amino carboxylic acid or derivative; from a polyamine and a polycarboxylic acid or derivative

<http://www.uspto.gov/.../sched525.htm> - Cached

Class Schedule for Class 528 SYNTHETIC RESINS OR NATURAL RUBBERS ...

Reactant which contains at least two -C-C(=X)-X-C groups has been derived from only a dicarboxylic acid or derivative and only a dihydric alcohol or alcoholate derivative

<http://www.uspto.gov/.../sched528.htm> - Cached

Class Schedule for Class 521 SYNTHETIC RESINS OR NATURAL RUBBERS ...

At least one polymer is derived from a polycarboxylic acid or derivative and a polyol or wherein the polymer-forming system containing the same type of reactants

<http://www.uspto.gov/.../sched521.htm> - Cached

Class Definition for Class 536 - ORGANIC COMPOUNDS -- PART OF THE ...

Erythromycin or derivative (e.g., oleandomycin, etc.): This subclass is indented under subclass 7.1. Compounds which have the following structure and derivatives thereof wherein ...

Applicants submit that the polyvinyl acetate derivatives and modified starches claimed are conventional, well known components to those ordinarily skilled in the art. Further, as the terminology utilized in the pending claims that the Examiner finds improper or unsupported by the original disclosure is standard patent parlance fully supported under the U.S. Patent and Trademark guidelines, Applicants submit that one ordinarily skilled in the art would readily understand how to make and use the claimed encapsulated products using the claimed polyvinyl acetate derivatives and modified starches, even without express disclosure of all possible species of polyvinyl acetate derivatives and modified starches in Applicants' disclosure.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTIONS UNDER 35 USC 112, SECOND PARAGRAPH

Claims 25-31, 34, 35, 37, 38, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 82, 83, 91-93, 95-97, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner maintains that the term "substantially" adds a degree of variation that has not been defined in any limiting way and is, therefore, a relative term which renders the claims indefinite. According to the Examiner, in light of the specification, it is not known what degree of dextrinization would fall within the limits of the instant claims because the limits are not defined., such as 0% dextrinization or 10% dextrinization. The Examiner maintains that this is also the case for the "homogeneity," "non-expanded" nature and "non-cellular" structure of the compositions.

However, the recitation of specific percentages are not required for definiteness of a claim. According to MPEP 2173.05(b) the fact that claim language, including terms of

degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. The specification provides general guidelines and that is sufficient to satisfy the requirements of 35 USC 112, second paragraph. Those skilled in the art would know what is meant by substantially homogeneous mixture, substantially non-expanded, substantially non-cellular structure, and not substantially dextrinized in light of the specification and the Examiner has not demonstrated otherwise. Indeed, the Examiner has correctly interpreted the claim for purposes of examination apparently on the basis of reading Applicant's disclosure. For example, the present specification gives guidance as to a substantially non-expanded, non-cellular structure, by providing exemplary specific densities at page 10 lines 1-2 where it is recited that "The specific density of the pellets or particles may be from about 800 g/liter to about 1500 g/liter."

Also, guidance to avoid substantial dextrinizing and destructurizing of starch is provided, for example, by way of extrusion operating conditions, such as temperature, pressure, shear, residence time, and degree of starch gelatinization. For example, at pages 22-23 it is recited:

In accordance with the method of the present invention, the matrix material or plasticizable material and the plasticizer are admixed and heated to plasticize and melt the matrix material under low shear mixing conditions without substantially destroying or decomposing the matrix material. In preferred embodiments, the matrix material and the plasticizer may be added to the upstream end of an extruder, mixed and heated above the melt temperature of the plasticizable material or above the gelatinization temperature of starch while mixing and conveying these ingredients inside the extruder. In embodiments where starch is used as a matrix material, the starch is at least partially gelatinized without substantially deconstructuring and dextrinizing the starch. The degree of gelatinization may, for example, be at least about 75%, for example, at least about 90%, or essentially completely gelatinized. In embodiments of the invention, to achieve at least substantial gelatinization of starch, the starch and plasticizer (preferably water) admixture may be maintained at a temperature of the blend of at least about 100°C, preferably from about 120°C to

about 150°C, for example, from about 125°C to about 140°C, for a period of time of at least about 3 l/d preferably about 5 to 7 l/d of extruder length. For example, for starches having an amylose content of more than about 25%, for example about 50% to about 70%, it may be necessary to maintain a product temperature inside the extruder of about 125°C for a sufficient amount of time, for example for about 4 l/d, preferably about 7 to 8 l/d of extruder length at a low screw rotational rate of about 150 to about 200 rpm using medium pitch screw elements to assure at least substantial gelatinization of the starch.

In embodiments of the invention, the pressure maintained within the cooking section or gelatinization section or plastification zone may be between about 5 to 100 bars, preferably between about 10 and 35 bars.

An overall quantitative measure of the shear used inside the extruder during the cooking process is the specific mechanical energy input. In embodiments of the present invention, the specific mechanical input during cooking may be below about 150 Wh/kg, preferably below about 100 Wh/kg, and most preferably below about 50 Wh/kg.

See also pages 29, 30, 32, 33, and 36 where conditions for avoiding excessive dextrinization are also provided.

Additionally, guidance to obtain a substantially homogeneous mixture is provided, for example, by way of the above conditions as well as the description of extrusion equipment screw configuration, and screw speed, at, for example page 25 where it is recited:

The admixing of the added active ingredients or encapsulants inside the extruder may be accomplished by using an appropriate extrusion screw configuration for achieving low shear mixing. For example, a combination of alternating small pitch conveying elements with distributive mixing elements, that are staggered at an angle to each other for providing axially oriented leakage flow inside the extruder barrel may be employed. The combination of alternating conveying elements with distributive mixing elements cause the material flow to be continuously interrupted without shearing of the mass thus resulting in mixing of the material at low mechanical energy input.

In other embodiments of the invention, other extruder screw configurations may be used that facilitate low shear distributive mixing, such as screw elements of the type ZME, TME, SME, and so-called IGEL elements commercially available from Werner and Pfleiderer.

The total length of the distributive mixing section may be about 3 to 12 l/d, preferably about 4 to 6 l/d to sufficiently admix and distribute and embed or encapsulate the added active components in the matrix.

The at least substantially homogeneous mixture of matrix material and added active ingredient or encapsulant is then conveyed towards an extruder die plate.

It is accordingly submitted that the rejection on the grounds that the term “substantially” is indefinite should be withdrawn.

The rejection of claims 31, 59, 108, and 109 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of use of the terms “derivative” and “modified starch” is untenable for reasons as given above with respect to the rejection under the first paragraph of 35 U.S.C. 112. As discussed above, the term “modified starch” and the extent of modification is well known to those skilled in the art as exemplified in the USPTO online Manual of Classification class definition for Class 127, subclasses 32, 33, and 38. Also, discussed above, the term “derivative” is well known to those skilled in the art as exemplified by the extensive use of the term in the USPTO class definitions. Additionally, the terms are well known as further exemplified by Newton et al (USP 4,938,967) at col. 8 lines 61-65, and col. 9 lines 18-29, and Wittwer et al (USP 4,738,724) at col. 7 line 67 to col. 8 line 24.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTIONS UNDER 35 U.S.C. 103

Claims 25, 27-30, 34, 35, 37-40, 46, 50, 52, 54-58, 61, 62, 64-67, 73, 75, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of newly cited Lay et al (U.S. Patent No. 5,095,054). This rejection is respectfully traversed.

Newton et al does not teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, or particles where an encapsulant is dispersed throughout the plasticized mass of each particle, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims.

The Examiner employs Newton et al as teaching pharmaceutical compositions. The Examiner admits that Newton et al does not disclose the exact amounts of matrix material or encapsulant, but concludes that the amounts claimed, such as the amount of matrix material, is a result effective variable. However, the Examiner has not presented any evidence, by way of references or otherwise, to establish that the amount of matrix material is a result effective variable.

The Examiner maintains that Newton et al discloses that generally water is added to the compositions to aid in pelletization, encompassing a water plasticizer, and thus it would appear that the presence of a plasticizer would lead to a plasticized mass. However, just because a plasticizer may be present does not mean that a matrix material such as starch is plasticized. As disclosed in the present specification, a sufficient amount of water and high temperatures are needed to gelatinize starch and produce a plasticized matrix from starch. See, for example, page 7 lines 4-15, page 8 line 22 to page 9 line 5, and page 22 line 12 to page 23 line 3. Mere mixing of starch and water does not produce a plasticized mass as claimed. As demonstrated by the data shown in Table 1 and FIG. 6, in Comparative Example 2 (M1) pure starch does not present a sufficient matrix for encapsulation, because the time to release 100% of the encapsulant is too short.

Newton et al employs a weighting agent to increase density beyond normal levels to thereby increase release time. The weighting agent generally is employed in an amount of at least 50% by weight of the unit, and generally has a density of at least 2.5 g/ml. The weighting agent may be a powder such as barium sulphate, ferric oxide, ferrum redactum, titanium dioxide and aluminum oxide or hydroxide, calcium carbonate, barium phosphate, bismuth phosphate, calcium aluminosilicate, zirconium silicate, calcium phosphate, silicon carbide, and magnesium carbonate. See col. 4 lines 33-52, col. 5 lines 7-9, col. 9 line 43 to

col. 10 line 1. Newton et al discloses the use of a conventional matrix binder which may be a synthetic polymer or natural polymer or derivative such as starch or preferably cellulose or its derivatives. A known gastric controlled release binder may also be employed such as hydrophobic acrylic polymers or cellulose derivatives, vinyl polymers and other high molecular weight natural polymer derivatives or synthetic polymers. See col. 8 line 61 to col. 9 line 36. Each unit may comprise a homogeneous or non-homogeneous blend of the active ingredient and the weighting agent and any matrix binder component. For instance each unit may have a core of weighting agent covered by a shell of active ingredient or vice versa or it may be formed of a blend of the active ingredient and the weighting agent. See col. 10 lines 58-64. The preferred method for forming the pellets or other units is to make a mixture of the weighting agent and the active ingredient and matrix binder and then to form the mixture into the units. Generally some water is added to the mixture to aid pelletization. See col. 11 lines 34-44. Use of starch as a conventional matrix binder would result in rapid release properties, and necessitates the use of a weighting agent to increase density and increase release time in accordance with the disclosure of Newton et al.

Newton et al does not teach or suggest use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, and there is no reason to do so. Furthermore, admixing a starch with the encapsulant and the weighting agent, and heating the mixture to plasticize the starch would destroy the encapsulant. There is no teaching, suggestion, or expectation that plasticizing the starch binder of Newton et al, would have a beneficial effect on the release properties of the Newton et al composition and would not destroy the encapsulant.

The Examiner asserts that it is reasonable to assume that the starches of the Newton et al reference are not substantially dextrinized because they do not appear to be heated. However, if they are not heated, the Examiner has not established that they are plasticized, or provided any reasons why it would be obvious to plasticize the starches of Newton et al, or provided an explanation as to how to plasticize the starches without substantially deconstructuring or dextrinizing the starch.

Lay et al relates to polymer compositions capable of being formed by heat and pressure into articles having dimensional stability and enhanced physical properties, and to pre-mixes useful for preparing these compositions. These compositions and pre-mixes comprise destructurized starch. See col. 1 lines 41-47. Lay et al does not cure the deficiencies in the disclosure of Newton et al, and even if the references were properly combinable, applicant's claimed invention would not be obtained nor rendered obvious.

The starches employed by Lay et al show an improved dimensional stability in humid air whilst retaining a surprisingly high degree of disintegration in contact with moisture water which in consequence leads to a high degree of biodegradability (page 3, lines 13-20). Clearly, Lay et al employs a starch which disintegrates unexpectedly rapidly in water to provide a high degree of biodegradability. The destructurized starch of Lay et al has been heated to a high enough temperature and for a time long enough so that the specific endothermic transition analysis as represented by differential scanning calorimetry (DSC) indicates that a specific relatively narrow peak just prior to oxidative and thermal degradation has disappeared. See col. 2 lines 1-48. The reference teaches away from thermoplastic starch because processing parameters such as water content, temperature, and pressure are generally critical, and must be narrowly controlled to achieve reproducible quality products. See col. 2, lines 42-48.

Lay et al desires destructuring of starch and degradation to achieve rapid water solubility and rapid biodegradability, and does not teach or suggest avoidance of substantial destructuring or dextrinization of starch. As disclosed in the present specification, high shear is directly related to high specific mechanical energy, which in turn increases the molecular destructurization and dextrinization of starch. Breakdown of the starch molecules, and in particular the amylopectin, increases the solubility of the extruded starch composition in aqueous systems. As disclosed in the present specification, high water contents, and low shear and low extruder screw speeds are employed to avoid substantial dextrinization of starch and to provide a controlled release of encapsulant rather than an

unexpectedly rapid disintegration in water for unexpectedly high biodegradability. See pages 3, 6, 7, 9, 22, 29, 32, 33, and 36 of the present specification.

The references simply do not teach or suggest obtaining a plasticized matrix material while avoiding substantial destructuring or dextrinization of starch.

As to the amount of matrix material and as to the release profile recited in claims 38 and 65, the Examiner maintains that it would take no more than routine skill in the art to adjust the amount of binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65. However, Newton et al teaches that it is difficult to maintain prolonged drug availability in a chosen environment such as the stomach by choice of a binder, and that there is an urgent need to provide an entirely new mechanism by which it is possible to provide prolonged release of an active ingredient within the stomach. The mechanism employed by Newton et al is the use of a weighting agent to increase density. See col. 1 line 20 to col. 2 line 10, and col. 4 lines 33-62. Thus, contrary to the position taken by the Examiner, Newton et al teaches away from use of a binder to achieve a desired active release profile. There is no reason to modify the composition of Newton et al to change the release time as proposed by the Examiner because it is contrary to the reference's teaching.

Additionally, with regard to claims 82 and 85 none of the references teach or suggest the encapsulation of an enzyme or microorganism and none of the references teach or suggest the encapsulation of a liquid encapsulant as claimed in claim 93.

The Examiner indicates that it is believed that Newton et al meets the limitations of the instant claims, but for *arguendo* in the case that the plasticized mass is obtained by heating the matrix material in the presence of a plasticizer such as water, the following rejection is made. It is noted that the present rejection is made in view of Lay et al in the preamble of the rejection, but the Lay et al reference is not discussed. In this regard, for reasons as set forth above, Newton et al taken alone or in combination with Lay et al does not teach or suggest the claimed invention.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of newly cited Lay et al (U.S. Patent No. 5,095,054). This rejection is respectfully traversed.

In this rejection, the Examiner admits that Newton et al does not disclose the starch is plasticized by heating. As discussed above, Newton et al does not disclose production of a plasticized mass with or without heating. As explained above, just because a plasticizer may be present does not mean that a matrix material is plasticized. As disclosed in the present specification, a sufficient amount of water and high temperatures are needed to gelatinize starch and produce a plasticized matrix from starch. See, for example, page 7 lines 4-15, page 8 line 22 to page 9 line 5, and page 22 line 12 to page 23 line 3. Mere mixing of starch and water does not produce a plasticized mass as claimed. As demonstrated by the data shown in Table 1 and FIG. 6, in Comparative Example 2 (M1) pure starch does not present a sufficient matrix for encapsulation, because the time to release 100% of the encapsulant is too short.

The Examiner now maintains that it would have been obvious to one ordinarily skilled in the art to have used a heated plasticized starch matrix in the formulations of Newton et al motivated by the desire to use a composition that forms articles having dimensional stability and enhanced physical properties suitable for use in pharmaceutical formulations for delivering actives, as disclosed by Lay et al.

As discussed above, Lay et al relates to polymer compositions capable of being formed by heat and pressure into articles having dimensional stability and enhanced physical properties, and to pre-mixes useful for preparing these compositions. These compositions and pre-mixes comprise destructurized starch. See col. 1 lines 41-47. Lay et al does not cure the deficiencies in the disclosure of Newton et al, and even if the references were properly combinable, applicant's claimed invention would not be obtained nor rendered obvious.

The starches employed by Lay et al, show an improved dimensional stability in humid air whilst retaining a surprisingly high degree of disintegration in contact with moisture water which in consequence leads to a high degree of biodegradability (page 3, lines 13-20). Clearly, Lay et al employs a starch which disintegrates unexpectedly rapidly in water to provide a high degree of biodegradability. The destructurized starch of Lay et al has been heated to a high enough temperature and for a time long enough so that the specific endothermic transition analysis as represented by differential scanning calorimetry (DSC) indicates that a specific relatively narrow peak just prior to oxidative and thermal degradation has disappeared. See col. 2 lines 1-48. The reference teaches away from thermoplastic starch because processing parameters such as water content, temperature, and pressure are generally critical, and must be narrowly controlled to achieve reproducible quality products. See col. 2, lines 42-48.

Lay et al desires destructuring of starch and degradation to achieve rapid water solubility and rapid biodegradability, and does not teach or suggest avoidance of substantial destructuring or dextrinization of starch. As disclosed in the present specification, high shear is directly related to high specific mechanical energy, which in turn increases the molecular destructurization and dextrinization of starch. Breakdown of the starch molecules, and in particular the amylopectin, increases the solubility of the extruded starch composition in aqueous systems. As disclosed in the present specification, high water contents, and low shear and low extruder screw speeds are employed to avoid substantial dextrinization of starch and to provide a controlled release of encapsulant rather than an unexpectedly rapid disintegration in water for unexpectedly high biodegradability. See pages 3, 6, 7, 9, 22, 29, 32, 33, and 36 of the present specification.

The Examiner points out that Lay et al discloses that the polymer compositions may be formed into granules and powder and they may act as carrier materials for active agents, and may be mixed with active ingredients such as pharmaceuticals and/or agriculturally active compounds such as insecticides or pesticides for subsequent release applications of these ingredients. However, mixing the active ingredients with the polymer composition

granules or powder would result in coating of the active ingredients on the granule or powder particles and would not result in a particle with the active ingredient being dispersed throughout a plasticized mass as claimed.

Furthermore, Newton et al desires to increase gastric residence time by increasing density which is the opposite effect of an unexpectedly rapid disintegration in water desired by Lay et al. Also, to increase density, Newton et al employs a weighting agent with a density of at least 2.5 g/ml in an amount of 50% by weight, based on the dry weight of the unit, which is an inorganic compound such as magnesium trisilicate, magnesium oxide, aluminum oxide, zinc oxide , and the like. See Newton et al at col. 9 line 51 to col. 10, line 18. Combining the disclosures of the references as proposed by the Examiner simply would not result in nor render obvious a particle with the active ingredient being dispersed throughout a plasticized mass comprising a starch which is not substantially destructureized or dextrinized as claimed.

As to the amount of matrix material and as to the release profile recited in claims 38 and 65, the Examiner maintains that it would take no more than routine skill in the art to adjust the amount of binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65. However, increasing the release time is not desired by Lay et al because it is contrary to the reference's teaching and desire for an unexpectedly rapid disintegration in water.

Additionally, with regard to claims 82 and 85 none of the references teach or suggest the encapsulation of an enzyme or microorganism and none of the references teach or suggest the encapsulation of a liquid encapsulant as claimed in claim 93.

The references simply do not teach or suggest obtaining a plasticized matrix material while avoiding substantial destructureing or dextrinization of starch, and achieving a particle with the active ingredient being dispersed throughout a plasticized mass comprising a starch.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 42, 69, 70, 84, and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of newly cited Lay et al (U.S. Patent No. 5,095,054) as applied above, in further view of Jane et al (U.S. Patent No. 5,397,834). This rejection is respectfully traversed.

The Examiner admits that Newton et al. and Lay et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. The Examiner points out that Jane et al discloses biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein, that suitable starches include those derived from durum wheat, and that the reference differs from the instant claims in so far as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Jane et al does not cure the deficiencies in the disclosures of Newton et al and Lay et al discussed above, and even if it were obvious to combine the teachings of Newton et al, Lay et al, and Jane et al, applicant's claimed invention would not be obtained nor rendered obvious. The Examiner maintains that Newton et al and Lay et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. As discussed above, Newton et al and Lay et al, even if properly combinable, do not teach or suggest particles where for each particle an encapsulant is dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized. Even if it were obvious to employ a starch derived from durum wheat in the product of Newton et al, which it is not, Applicant's claimed products would not be obtained nor rendered obvious.

Moreover, a starch which is derived from durum wheat is not the same as durum wheat which has different matrix forming properties and different release properties. Durum wheat contains gluten which forms a plasticizable starch-protein matrix, and as disclosed in the present invention, heating or cooking of durum wheat to gelatinize starch is not required. Use of starch derived from durum wheat would not include the gluten and would result in a different matrix and different release properties.

Serial No. 09/782,320
AMENDMENT UNDER 37 C.F.R. 1.111
Attorney Docket No. BVL-102A

The rejection is untenable and reconsideration and withdrawal thereof is respectfully requested.

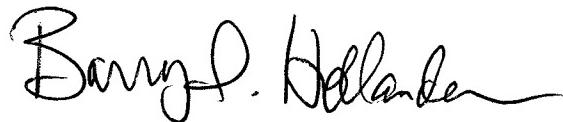
CONCLUSION

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

It is not believed that any additional fees are due. However, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,

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